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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,120	07/18/2001	Dana Ault-Riche	25885-1751	1666

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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/910,120	AULT-RICHE ET AL.	
	Examiner	Art Unit	
	My-Chau T. Tran	1639	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37,49-54,93-95 and 99* is/are pending in the application.

4a) Of the above claim(s) *11-16,23,25-32,34,35,49-54,94,95 and 99* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,17,19-22,24,33,36,37 and 93* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ ~~Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)~~ Paper No(s)/Mail Date *see Office Action*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 10/7/03 is acknowledged and entered. Claims 2-4, 8-9, and 25 are amended by the amendment. It is noted that claims 8-9 are also amended because in the claim listing claims 8-9 showed changes to the claims.

2. Applicant's amendment filed 12/27/03 in Paper No. 11 is acknowledged and entered. Claims 34-48, 55-92, and 96-98 are canceled. Claim 99 is added. Claims 1-37, 93-95, and 99 are pending.

3. Claims 1-37, 93-95, and 99 are pending.

Election/Restrictions

4. Applicant's election with traverse of Group I (Claims 1-37, 93-95, and 99) in Paper filed on 12/27/03 and 10/7/03 is acknowledged.

The traversal is on the ground(s) that Group III (Claims 49-54) should be joined with Group I because Group I and Group III should be restricted as being '[r]elated as a combination/subcombination for which a showing of two-way distinctness is required'.

This is not found persuasive because these inventions are "structurally" distinct and each group involved different patentability considerations. The patentability determination of Group I (array (i.e. a combination)) would involve a determination of the patentability of the array of a composition comprised of capture agents and oligonucleotides (independent of its use) while the

patentability determination of Group III (apparatus) would involve a determination of the patentability of the combination of a system comprised of an array (i.e. combination) and a computer system (independent of its use). These considerations are very different in nature. Additionally if Group I and Group III are restricted as being related as combination/subcombination, the combination (Group III) as claimed does not require the particulars of the subcombination (Group I) as claimed because the subcombination does not need to be the claimed array (i.e. combination) comprising capture agents and oligonucleotides. For example, the array would include such combination as antibodies and protein tag (see Example 1 of specification), or other combination of receptors and ligands such as antibodies and antigen, proteins and peptidomimetric proteins. The subcombination has separate utility such as a probe for assay screening for enzymes, or nucleic acid.

The requirement is still deemed proper and is therefore made **FINAL**.

5. Claims 49-54 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on 12/27/03 and 10/7/03.

6. Applicant's species election with traverse in Paper filed on 10/7/03 is acknowledged. The elected species are follows:

a. Capture agents: antibodies

b. Oligonucleotide: '[o]ligonucleotide comprises a polypeptide-encoding region (*i.e.*, has formula 5'-E_m-3'), where each polypeptide that binds to a capture agent is encoded by a region designated E_m that is at least about 14 nucleotides'.

The traversal is on the ground(s) that "[F]irst, the oligonucleotides are not attached to the capture agent, and second, it makes no sense to elect a single capture agent or single oligonucleotide, since the claims are directed to combinations that include collections of each".

This is not found persuasive because the presently claimed combination can be interpreted at least two ways. The presently claimed array (i.e. combination) briefly recites a combination of capture agents and oligonucleotide wherein the oligonucleotide comprises nucleotides that encodes a preselected polypeptide to which the capture agent binds (Claims 1 and 17) (i.e. the oligonucleotides are "attached" to the capture agent). For example, the combination can be interpreted as an array of probes (capture agent) that binds (i.e. *the point of attachment to the capture agent*) to the analyte (oligonucleotide) or an array of probes that comprises of a combination of capture agent and oligonucleotide wherein they are 'link' (i.e. *the point of attachment to the capture agent*). Thus each interpretation combination comprises several structurally distinct species because within each genus of capture agents and oligonucleotides there are several structurally distinct species.

The requirement is still deemed proper and is therefore made **FINAL**.

7. Claims 11-16, 23, 25-32, 34-35, 94-95, and 99 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable

generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on 10/7/03.

Priority

8. Applicant's claim for domestic priority under 35 U.S.C. 119(e) to a provisional application number 60/219,183 is acknowledged.

Information Disclosure Statement

9. The information disclosure statement(s) (IDS) submitted by applicant filed on 8/12/02; 10/9/02, and 7/2/03 are acknowledged and considered.

10. Claims 1-10, 17-22, 24, 33, 36-37, and 93 are treated on the merit in this Office Action.

Claim Objections

11. Claim 18 is objected to because of the following informalities: Claim 18 is dependent on "claim X". Appropriate correction is required. However in order to further prosecution, claim 18 is interpreted to depend on claim 1.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-6, 8-9, 17, 19-20, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Huston et al. (Us Patent 5,084,398).

Huston et al. disclose an array (combination) comprises antibodies (capture agents) and oligonucleotides that are encoded with a protein-binding site specific to the antibodies (Abstract; col. 2, lines 10-23; col. 5, lines 24-37; fig. 2). The antibodies are immobilized on a solid support (col. 2, lines 30-41; col. 5, lines 38-52). The amino acid sequence that is encode by the oligonucleotide has a length greater than 2 (i.e. m of 5'-E_m-3' is greater than 2) (fig. 2) and the oligonucleotide is single-stranded). Therefore the array of Huston et al. anticipates the presently claimed invention.

14. Claims 1-10, 17-22, 33, and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Wagner et al. (US Patent 6,329,209 B1).

Wagner et al. disclose an array of protein-capture agents wherein the protein-capture agent is immobilized on the substrate surface to form a plurality of patches of protein-capture agents on discrete, known regions (addressable array) of the surface of a substrate (col. 3, lines 58-67 to col. 4, lines 1-2). The protein-capture agents are immobilized through an affinity tags that have specific affinity to the protein-capture agents onto the substrate surface (linked indirectly to a solid support) (col. 20, lines 59-62; col. 21, lines 19-). The affinity tags (oligonucleotides) comprises of polypeptides that are encoded by a DNA sequence (col. 21, lines 25-28; col. 60-64). Protein-capture agent includes antibodies (col. 4, lines 48-67). The array can have any number of a plurality of different protein-capture agents (col. 11, lines 1-11). For

instance, an array comprise of about 10,000 patches would comprise of about 10,000 different protein-capture agents (col. 11, lines 28-33). Therefore, the number of different protein-capture agents on an array will vary depending on the application desired (col. 11, lines 12-13). Therefore the array of Wagner et al. anticipates the presently claimed invention.

15. Claims 1-10, 17-22, 24, 33, 36-37, and 93 are rejected under 35 U.S.C. 102(b) as being anticipated by Iris et al. (US Patent 6,403,309 B1).

Iris et al. discloses an array of antibody that captures oligonucleotide probes labeled with peptide tags (oligonucleotide encoding polypeptide) (col. 1, lines 14-18; col. 2, lines 34-47). The solid phase surface comprises a plurality of loci, wherein each locus comprises an antibody specific to one or more of the peptides of the peptide label oligonucleotide probes (col. 6, lines 28-31; col. 22, lines 23-29). The peptide tags are specific to the antibodies of the array (col. 21, lines 29-39). Further, the oligonucleotide probes may be first hybridized to a target DNA before being capture by the addressable antibody arrays (col. 15, lines 32-67 to col. 16, lines 1-11). Therefore, the array of Iris et al. anticipates the presently claimed invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 571-272-0810. The examiner can normally be reached on M: 8:00 -2:30; Tues-Thurs.: 7:30-5:00; F: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mct
February 23, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER